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| APPLICATION NO.                                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/084,160  | 02/28/2002  | Shuji Kaneko         | 220125US0 X         | 4862             |
| 22850   | 7590        | 01/18/2005           | EXAMINER            |                  |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. |             |                      | JONES, DWAYNE C     |                  |
| 1940 DUKE STREET                                  |             |                      | ART UNIT            |                  |
| ALEXANDRIA, VA 22314                              |             |                      | PAPER NUMBER        |                  |

1614

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/084,160

Applicant(s)

KANEKO ET AL

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on the amendment and remarks of 30 NOV 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,9-14 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,2 and 9-14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1, 2, 9-14, and 21-36 are pending.
2. Claims 21-36 are rejected.
3. Claims 1, 2, and 9-14 are non-elected and withdrawn from consideration.

### ***Response to Arguments***

4. Applicants' arguments with respect to claims 21-36 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 22, 26-28, and 36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Marston et al. of WO 98/27930 possessing a publication date of July 2, 1998. Marston et al. teach of the aminopiperaziny compounds of formula (I) as well as its pharmaceutically acceptable salts thereof for the treatment of inter alia schizophrenia, spinal cord injury, ADHD, narcolepsy and Parkinson's disease, (see pages 1-6). In addition, the prior art reference of Marston et al. specifically teach of oral or parenteral administration of the aminopeperaziny compounds of formula (I) as well as its pharmaceutically acceptable salts thereof, (see page 7). The skilled artisan would consider the potentiation of a N-type  $\text{Ca}^{2+}$  channel activity as an inherent feature with

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the administration of these already known prior art aminopiperazinyl compounds. The courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art."

6. Claims 30-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Marston et al. of WO 98/27930 possessing a publication date of July 2, 1998. Claims 30-35 attempt to limit independent claim 21 by the incorporation of a product-by-process limitation on how the compound of claim 21 is obtained. In addition, these product-by-process limitations for claims 30-35 do not further limit the aminopiperazinyl compounds because these claims are defined as a product-by-process claim and is a product, not a process, see *In re Bridgeford*, 357 F2d 679, 149, USPQ 5 (CCPA 1966). It is the patentability of the product claimed and not of the recited process steps which must be established, see *In re Brown*, 459 F2d 531, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 541 F2d, 191 USPQ (CCPA 1976). A comparison of the recited process with the prior art processes does not serve to resolve the issue concerning the patentability of the product, see *In re Fessman*, 489 F2d 742, 180 USPQ 324 (CCPA 1974). For these reasons, Marston et al. do in fact teach of the administration of aminopiperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof for the treatment of inter alia schizophrenia, spinal cord injury, ADHD, narcolepsy and Parkinson's disease, (see pages 1-6). The skilled artisan would consider the potentiation of a N-type  $\text{Ca}^{2+}$  channel activity as an inherent feature with the administration of these already known prior art aminopiperazinyl compounds. The

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courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art." In addition, the prior art reference of Marston et al. specifically teach of oral or parenteral administration of the aminopeperaziny compounds of formula (I) as well as its pharmaceutically acceptable salts thereof, (see page 7).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 21-29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Marston et al. of WO 98/27930 possessing a publication date of July 2, 1998. Marston et al. teach of the aminopiperaziny compounds of formula (I) as well as its pharmaceutically acceptable salts thereof for the treatment of inter alia schizophrenia, spinal cord injury, ADHD, narcolepsy and Parkinson's disease, (see pages 1-6). In addition, the prior art reference of Marston et al. specifically teach of oral or parenteral administration of the aminopeperaziny compounds of formula (I) as well as its pharmaceutically acceptable salts thereof, (see page 7). Marston et al. further teach of various dosages of these compounds to mammals, (see pages 1, lines 6-13, page 3, lines 12-18 and page 7). The skilled artisan would consider the potentiation of a N-type  $\text{Ca}^{2+}$  channel activity as an inherent feature with the administration of these already known prior art aminopiperaziny compounds. The courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art." The instant method differs only in the specific range of dosages and modes of administration. The determination of a dosage having the optimum therapeutic index while minimizing adverse or unwanted side-effects is well within the level of the skilled artisan, and the artisan would be motivated to determine optimum amounts as well as modes and

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methods of administration in order to get the maximum effect of the drug. Hence, the Marston et al. reference makes obvious the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.


Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources.

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DWAYNE JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614  
January 10, 2005